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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,691	SHIDHAM ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/09/05, 02/06/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 18 and 21-35 are objected to because of the following informalities:

In regards to claim 18, at line 2, "the mouth" should apparently read --a mouth thereof-- so as to avoid a potential lack of antecedent basis problem.

In regards to claim 21, at line 2, "the needle" should apparently read --a hub-- in order to avoid a potential indefiniteness problem.

In regards to claim 22, at line 7, the limitations "one or more" appears to render the claim indefinite and should apparently read --at least one of--. It is unclear whether or not the device comprises a plurality of hub and needle.

Further in regard to claim 22, at line 8, "the hub opening" should apparently --a hub opening-- to avoid a potential lack of antecedent basis problem.

In regards to claim 29, at line 2, "the position" should apparently read --a position-- to avoid a potential lack of antecedent basis problem.

In regards to claim 31, at line 10, the limitations "the device" appear to render the claim indefinite and should apparently read --the syringe--. It is unclear whether or not the hub is part of the device (see claim 22).

In regards to claim 35, at line 8, the limitations "one or more" appears to render the claim indefinite and should apparently read --at least one of--. It is unclear whether or not the device comprises a plurality of hub and needle.

Appropriate correction is required.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 20, second occurrence, has been renumbered --30--.

Misnumbered claims 37-39 have been renumbered --36-38--, respectively.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6-8, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by DeVries (US Patent No. 4,967,762).

In regards to claim 1, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device comprising:

a hub 40 defining a specimen collection well 62 and mounting a needle 70 having a shaft with an open pointed tip; and

a sample passageway 64 extending from the pointed tip of the needle 70 to a segment inside the hub opening in spaced relation to a floor of the collection well 62 (see figs. 1-2).

In regards to claim 2, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 defines the entire passageway 64 extending from the pointed tip to a contoured proximal end. (see fig. 2).

In regards to claim 3, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 defines an opening 64 in the floor of the collection well 62 through which the needle shaft extends (see fig. 2).

In regards to claim 6, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the proximal end of the needle 70 in part follows the contour of the collection well 62 (see fig. 2).

In regards to claim 7, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the passageway 64 is defined in part by the needle 70 and in part by an internal channel in the hub 40 (see fig. 2).

In regards to claim 8, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 has a straight proximal end disposed at an opening in the hub 40 defining an end of the channel (see fig. 2).

In regards to claim 16, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 includes an outer grip 52 (see figs. 1-2).

In regards to claim 17, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 has an open mouth 50 allowing access to the collection well 62 (see fig. 2).

5. Claims 22, 24-26, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellingson et al. (US Patent No. 6,217,556).

In regards to claim 22, Ellingson et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device 10, comprising:

a syringe 61 including a barrel 63 and a piston 66 slidable within the barrel;

a valve 23 capable of controlling an opening in the syringe barrel;

a hub 53 linked to the valve 23 and defining a specimen collection well; and

a needle 12 mounted to the hub 53 having a shaft with an open pointed tip 14;

wherein one or more of the hub and needle define a passageway extending from the needle tip 14 to inside the hub opening in spaced relation to a floor of the collection well (see figs. 1-2).

In regards to claim 24, Ellingson et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 12 defines the entire passageway extending from the pointed tip 14 to a contoured proximal end (see fig. 2).

In regards to claim 25, Ellingson et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the passageway is defined in part by the needle 12 and in part by an internal channel in the hub 53 (see column 2/lines 56-60).

In regards to claim 26, Ellingson et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 12 has a straight proximal end disposed at an opening in the hub 53 defining an end of the channel (see fig. 2).

In regards to claim 36, Ellingson et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device comprising:

a syringe 61 including a barrel 63 and a piston 66 slidable within the barrel 63;

a valve 23 capable of controlling an opening in the syringe barrel 63; and

a hub 53 linked to the valve 23 and defining a specimen collection well, wherein the hub defines 53 an internal passageway capable of putting the collection well in communication with a lumen of a needle 12 (see figs. 1-2; column 2/lines 56-60).

In regards to claim 38, Ellingson et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the internal passageway opens to an interior of the collection well through an opening spaced from a floor of the collection well (see fig. 2).

6. Claims 22 and 31-34 rejected under 35 U.S.C. 102(b) as being anticipated by Markham (US Patent No. 4,549,554).

In regards to claim 22, Markham discloses a high specimen yielding anti-reflux needle aspiration biopsy device, comprising:

a syringe 10 including a barrel 12 and a piston 22 slidable within the barrel 12;

a valve 28 for controlling an opening in the syringe barrel 12;

a hub linked to the valve 28 and defining a specimen collection well (see figs. 1-2); and

a needle 36 mounted to the hub having a shaft with an open pointed tip;

wherein one or more of the hub and needle define a passageway extending from the needle tip to inside the hub opening in spaced relation to a floor of the collection well (see figs. 1-2).

In regards to claim 31, Markham discloses a method of needle aspiration biopsy using a device as recited in claim 22, comprising the steps of:

creating a vacuum in the syringe 10;

inserting the needle 36 into a specimen sample site;

communicating the vacuum to the needle 36 (see figs. 1-2);

probing the specimen sample site with the needle 36 to collect specimens in the collection well of the hub;

releasing the vacuum in the needle 36;

withdrawing the needle 36 from the specimen sample site;

separating the hub from the device; and

transferring specimens collected in the hub to an examination site (see figs. 1-2) column 4/lines 23-28, 37-43 & 59-64).

In regards to claim 32, Markham discloses a method of needle aspiration biopsy wherein the step of creating a vacuum in the syringe 10 includes closing the valve 28 and pulling the syringe piston 22 away from the syringe barrel 12 (see column 4/lines 23-28).

In regards to claim 33, Markham discloses a method of needle aspiration biopsy wherein the vacuum is communicated to the needle 36 by opening the valve 28 (see column 4/lines 37-43).

In regards to claim 34, Markham disclose a method of needle aspiration biopsy wherein the step of releasing the vacuum in the needle 36 includes reclosing the valve 28 (see column 4/lines 59-64).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 4-5 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Dysarz (US Patent No. 6,589,209).

In regards to claims 4-5 and 10-11, Devries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries does not teach a needle segment that extends along and opens about a lateral axis at an angle to a longitudinal axis. However, Dysarz discloses a needle aspiration device wherein the proximal end of the needle includes a segment that extends along and opens about a lateral axis at an angle to a longitudinal axis of the needle; wherein the lateral and longitudinal axes are essentially perpendicular (see fig. 21A). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a needle aspiration device with a needle segment similar to that of Dysarz in order to provide the needle with a safer connection that would resist slippage thereof.

In regards to claim 9, Devries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries does not teach a proximal end of the needle that has raised barbs. However, Dysarz discloses a needle aspiration device wherein the proximal end

of the needle includes raised barbs (see column 2/lines 18-20). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a needle aspiration device with connection similar to that of Dysarz in order to provide the needle with a safer connection that would resist slippage thereof.

9. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Weis-Fogh (US Patent No. 6,284,285).

Devries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries does not teach a collection well containing an anti-coagulant surface. However, Weis-Fogh discloses a collection bag that containing an anti-coagulant; wherein the anticoagulants include ACD or EDTA (see column 7/lines 46-51). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a collection well similar to that of Devries with an anticoagulant similar to that of Weis-Fogh in order to prevent clotting of the sample.

10. Claims 14-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Ellingson et al. (US Patent No. 6,217,556).

In regards to claims 14-15, Devries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries does not teach a needle with an anti-friction surface. However, Ellingson et al. discloses a biopsy device comprising a needle with an anti-friction surface; wherein the anti-friction surface is a Teflon coating (see column 2/lines 27-29). It would have been obvious to one of ordinary skill in the art at the time

Applicant's invention was made to provide a biopsy device similar to that of Devries with a coating similar to that of Ellingson et al. in order to reduce friction.

In regards to claim 18, Devries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries does not teach a lid securable to the hub. However, Visconti discloses biopsy device comprising a lid 44 securable to a hub 53 (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Devries with a lid similar to that of Ellingson et al. in order to protect the sterility of the puncture site.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762).

Devries discloses a biopsy device head that teaches all the limitations of the claim except Devries does not expressly disclose that the collection well has a volume of at least 100 µL. The Examiner takes official notice that changing size is an obvious design choice that has previously been held to be unpatentable, see *In re Rose, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955).* As such, it would have been obvious to one of ordinary skill in that art at the time Applicant's invention was made to provide a collection well similar to that of Devries with a volume of at least 100 µL in order to collect a larger sample.

12. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Visconti (US Patent No. 5,743,883).

Devries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries does not teach a sheath stand defining an elongated cavity. However, Visconti discloses biopsy device comprising a sheath stand 24 defining an elongated cavity (see fig. 2). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Devries with a sheath similar to that of Visconti in order to contain the needle and protect the user from a potential needle stick.

13. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Banys et al. (US Patent No. 5,425,376).

Devries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries does not teach a needle defining a scoop opening at a side of the needle. However, Banys et al. disclose a needle 14 defining a scoop opening 28 at a side of the needle 14 (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Devries with a scoop opening similar to that of Banys et al. in order to assist in severing of a sample of a selected tissue (see Banys et al., column 5/lines 4-8).

14. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellingson et al. ('556) in view of Weis-Fogh ('285).

Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim

except Ellingson et al. do not teach a collection well containing an anti-coagulant surface. However, Weis-Fogh discloses a collection bag that containing an anti-coagulant; wherein the anticoagulants include ACD or EDTA (see column 7/lines 46-51). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a collection well similar to that of Ellingson et al. with an anticoagulant similar to that of Weis-Fogh in order to prevent clotting of the sample.

15. Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellingson et al. ('556).

Ellingson et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device comprising:

a syringe including a barrel and a piston slidable within the barrel; a valve for controlling an opening in the syringe barrel;

a hub linked to the valve and defining a specimen collection well; and

a needle mounted to the hub having a shaft with an open pointed tip;

wherein one or more of the hub and needle define a passageway extending from the needle tip to inside the collection well.

Ellingson et al. do not expressly disclose that the collection well has a volume of at least 100 μL or more than 500 μL. The Examiner takes official notice that changing size is an obvious design choice that has previously been held to be unpatentable, see *In re Rose, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955)*. As such, it would have been obvious to one of ordinary skill in that art at the time Applicant's invention

was made to provide a collection well similar to that of Devries with a volume of at least 100 µL or more than 500 µL in order to collect a larger sample.

16. Claims 29-30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellingson et al. ('556) in view of Banys et al. ('376).

In regards to claim 29, Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Ellingson et al. do not teach a a piston lock. However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Ellingson et al. with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

In regards to claim 30, Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Ellingson et al. do not teach a scoop opening. However, Banys et al. teach a scoop opening in the needle. However, Banys et al. disclose a needle 14 defining a scoop opening 28 at a side of the needle 14 (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Ellingson et al. with a scoop opening similar to that of Banys et al. in order to assist in severing of a sample of a selected tissue (see Banys et al., column 5/lines 4-8).

17. Claims 22-26, 27-28, 30, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Visconti (US Patent No. 5,743,883) in view of Devries ('762).

Visconti discloses a biopsy devices comprising:

In regards to claims 22 and 36, a syringe 12 including a barrel and a piston slidable within the barrel;

a valve 20 capable of controlling an opening in the syringe barrel (see figs. 1-2).

In regards to claim 23, further including a coupler containing the valve 20 and capable of connecting a hub to the syringe 12 (see figs. 1-2).

In regards to claim 28, Ellingson et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein further including a sheath stand 24 defining an elongated cavity for containing the needle and having an open end mountable to a hub (see fig. 2).

Visconti teaches all the limitations of the claims, as described in claims 22 and 36 except Visconti does not teach a biopsy device head. However, Devries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device comprising:

a hub 40 capable of being linked to a valve and defining a specimen collection well 62; and

a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;

wherein one or more of the hub and needle define a passageway 62 extending from the needle tip to inside the hub opening 64 in spaced relation to a floor 46 of the collection well 62 (see fig. 2).

In regards to claim 24, wherein the needle 70 defines the entire passageway extending from the pointed tip to a contoured proximal end (see fig. 2).

In regards to claim 25, wherein the passageway is defined in part by the needle 70 and in part by an internal channel 62 in the hub 40 (see fig. 2).

In regards to claim 26, wherein the needle 70 has a straight proximal end disposed at an opening in the hub 40 defining an end of the channel (see fig. 2).

In regards to claim 24, wherein the needle 70 defines the entire passageway extending from the pointed tip to a contoured proximal end (see fig. 2).

In regards to claim 38, wherein the internal passageway opens to an interior of the collection well 62 through an opening spaced from a floor 46 of the collection well 62 (see fig. 2).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Visconti with a biopsy head similar to that of Devries in order to obtain biopsy specimens (see Devries, Abstract, at lines 1-2).

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,413,115 to Baldwin discloses a biopsy syringe with a slide valve and a hub.

US Patent No. 4,799,494 to Wang discloses a percutaneous aspiration lung biopsy needle assembly.

US Patent No. 5,494,044 to Sundberg discloses a method for taking a sample of amniotic fluid.

US Patent No. 6,050,957 to Desch discloses a multiple-draw, variable suction syringe.

US Patent No. 3,757,981 to Harris, Sr. et al. discloses valves and valve needle syringes.

US Patent No. 3,557,778 to Hughes discloses a blood specimen collection assembly.

US Patent No. 4,931,044 to Beiter discloses a blood collection valve.

US Patent No. 3,957,052 to Topham discloses a pumping syringe and attachment for drawing.

US Patent No. 5,873,841 to Brannon discloses a syringe with decelerating device for blood collection.

US Patent No. 4,784,156 to Garg discloses a cannula including a valve structure and associated instrument elements and method of using same.

US Patent No. 4,366,822 to Altshuler discloses a method and apparatus for bone marrow cell separation and analysis.

US Patent No. 5,217,442 to Davis discloses an aspiration and refill kit for a medication infusion pump.

US Patent No. 2,697,437 to Everett discloses a hypodermic needle mounting.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT